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:Session 1: Challenges and available solutions for aseptic techniques

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Introduction

It is always the right time to talk about "Aseptic Processing and Techniques"

- Aseptic processing requires high composure, perseverance, and performance to result in the highest degree of control and assurance.
- Aseptic processing always requires right attitude and critical thinking.
- No single tool is perfect in completely eliminating the risk of a non-sterile unit.
- The challenges of aseptic process exist in every country and in every culture.

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Sterility Assurance Elements

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Perspective

Aseptic techniques and processes have always included the following:

- The design of facilities, equipment and the process.
- Qualification of facilities/ equipment and aseptic process validations (media fills, smoke studies, etc.) including routine process controls.
- Environmental monitoring and controls during aseptic manufacturing.
- Personnel qualification and practices in aseptic core.

Based on my experience, there are other challenges unique to India.

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Challenges

Aseptic Practices

- Cleanroom behavior outside the "cleanroom".
- Not just demonstrating proper techniques but operators need an in-depth understanding on purpose of the technique.
- Ability for operators to explain job functions.
- Culture that encourages open communication of the issues.

Consumables

- Critical or high risk consumables in aseptic area.
- Qualification of consumables before their use in aseptic manufacturing.
- Controls across the life cycle to assure and demonstrate these elements do not pose risk of product contamination.

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Challenges

Media Fills, Smoke Studies and EM Program

- Trending of interventions for aseptic process simulation.
- Ensure representative interventions are completed by operators.
- Smoke studies used to fullest extent.
- Meaningful environmental monitoring program.

Facility and Equipment Upgrades

- Legacy aseptic equipment with minimum barrier systems.
- Retro fit barriers/ glove ports on legacy systems.
- Facility maintenance.
- Power outages

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Potential Solutions

Transfers to Aseptic Core (Grade A)

➤ Establish procedure for transfer of various items during routine manufacturing activities and interventions (inherent and corrective).

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    graph LR
      A[Material Transfer] --> B[Evaluation]
      B --> C[Gaps]
      C --> D[Mitigation]
  
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Material Transfer

- Manufacturing material flow to clean areas
- Interventions requiring the material transfer
- Mapping of the aseptic processes

Evaluation

- Transfer practices and procedures
- Adequacy of the procedures
- Requirements for protective wrapping
- Load patterns in validation against floor SOP's
- Execution of aseptic interventions in sequences

Gaps

- Tool boxes
- Validation versus procedure versus practice
- Set-up process
- Controls for Cleanroom – particle (Viable and Non-viable) monitoring

Mitigation

- Procedure enhancements
- Continuous particle monitoring
- Primary & Secondary Operator concept (Doctor & Nurse)

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Potential Solutions

Management of Consumables

➤ Establish specifications and determine the quality attributes.

➤ Effective identification and evaluation by user to drive consumables handling and management approved supplier (with an audit/ qualification).

➤ Establish inspection controls across their life cycle.

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    graph LR
      A[Consumable] --> B[Consumable Category]
      B --> C[Evaluation by Quality]
      C --> D[Approved Consumable Vendor List]
      D --> A
  
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Consumable

- Identification
- Assessment (COA, Technical data etc)
- Categorization

Consumable Category

- Critical – Onsite Audit
- Major – Desktop Audit
- Minor – Suitability / rationale / justification

Evaluation by Quality

- Review of documents for adequacy
- Audit requirements
- Approval / Rejection
- Risk based approach for miscellaneous items

Approved Consumable Vendor List

- List of Approved Suppliers
- New Consumable Inclusion by Evaluation and Assessment

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Potential Solutions

Consumable Control

- Identification and qualification of the sterile commodities.
- Establish specifications and determine quality attributes.
- Implementation of statistical sampling/ testing and establishment of AQL.
- Checks to assure accuracy of the labeling and integrity of commodities.
- Incoming defect verification & usage controls.

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Potential Solutions

Personnel Training

- Best return on investment if done correctly.
- Leadership must support the time training will take and be prepared for how this time will impact operation schedules.
- Ultimately poor aseptic technique will result in a significant increase in costs.
- Teach **"why"** and not just **"what"**.
- Open communication at all levels encourage discussion on errors and improves performance.
- Constant reinforcement on floor and not in office.
- Perform "knowledge" audits of aseptic personnel.
- Aseptic core monitoring program to close the loop.

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Sustainable Compliance – Aseptic Processing

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Thank You

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